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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,412	10/27/2000	Haskell E. Mullins	56108USA1A.002	5638
32692	7590	12/13/2004	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			WIEKER, AMANDA FLYNN	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/698,412

Applicant(s)

MULLINS ET AL. 

Examiner

Amanda F. Wieker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 46 is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11, 13-15, 21, 24-30 and 32-37 is/are rejected.
- 7) ☒ Claim(s) 4, 12, 16-20, 22, 23, 31 and 39-45 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Drawings*

1. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required if the application is allowed.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-8, 11, 21, 24-27, 30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burström (FOA Report C40208-C1 (C2)) in view of Fennelly et al. ("An Automated Aerosol Generator to Reduce Variability in Qualitative Fit Testing of Respirators" K.P. Fennelly et al., American Journal of Respiratory and Critical Care Medicine Vol. 159, Supp #3 pages PA 615 DTD 199).

Burström discloses a system and method of qualitative respirator fit testing comprising providing a qualitative respirator fit testing system that comprises a plurality of test stations (individual head openings in tent) and an aerosol generator system (any of: tear gas torch, boiling tear gas tablet via stove or boiling tear gas tablet with a hot plate, driven by a car accumulator) in fluid communication with each of the test stations; locating at least one test subject at one test station; and conducting a qualitative fit test on each test subject located at one of the test stations, wherein the qualitative fit test comprises: delivering the test aerosol to the test station using the aerosol generator system after locating a respirator on the test subject,

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wherein the test subject is exposed to the test aerosol; and receiving test feedback (see page 5; feedback comprises “break off”, “adjust” or “exchange the mask and make a new attempt”) from the test subject at the test station after exposure to the test aerosol. The method of fit testing can be performed with two or more test subjects located at two or more of the test stations in the tent. Burström discloses that the aerosol generator system is in fluid communication with at least two of the plurality of test stations (see Figure 2, which shows that all of the test stations i.e., head openings, are in fluid communication with the inside of the tent, where the aerosol is generated). Consequently, aerosol generated by the generator will be applied to all test subjects simultaneously. Different selected amounts of aerosol can be delivered to the test stations by varying the size/density/composition of the generated aerosol (see page 4; from 200-500mg/m<sup>3</sup>). The test stations are monitored during testing (See cartoon on cover, for example). The test stations are considered to include a fit testing “hood”, due to the flaps extending outwardly from the tent, which hang over the test subjects’ heads like a hood, when the test subject is using the test station. Burström does not specify that the aerosol generator system comprise an automated aerosol generator system.

Fennelly et al. disclose a method of qualitative respirator fit testing, comprising administering a test aerosol to a test subject. Fennelly et al. specify that the aerosol be provided from an automated aerosol generator, to reduce error and fatigue when administering the aerosol to a large number of test subjects. The automated aerosol generator is fitted with a timer to deliver repeatable, selected amounts of aerosol at predetermined time intervals. Because the aerosol is generated by an automated nebulizer system, it is considered to be operated from a remote location (i.e., from a location not integral with the nebulizer; remote from the test subject).

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It would have been obvious to one skilled in the art at the time the invention was made to have provided the method of qualitative respirator fit testing as disclosed by Burström, wherein the aerosol generator is an automated aerosol generator system, as taught by Fennelly et al., to reduce error and fatigue when administering the aerosol to a large number of test subjects located in the plurality of test stations.

Regarding claims 35-36, it would have been obvious to have provided two such systems and methods of qualitative respirator fit testing since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. The system and method is fully capable of being duplicated, due to its economic production in mass quantities (see page 3).

4. Claims 9-10 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burström in view of Fennelly et al., in view of DE 26-52-136 to Pasternack.

Burström in view of Fennelly et al. disclose the previously described method and system for qualitative respirator fit testing, including the steps of delivering test aerosol and receiving test feedback from the test subject. Burström does not specify the storage of such information in a database.

Pasternack disclose a system and method for respirator fit testing involving administering a test aerosol to a test subject. Pasternack disclose the creation of a "data log", i.e., database, to record and compare data acquired during the respirator fit test.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the system and method for respirator fit testing as disclosed by Burström in view of Fennelly et al., wherein the accumulated data is stored in a database, as taught by Pasternack to allow the recording and comparison of test data.

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5. Claims 13-15 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burström in view of Fennelly et al., in view of Department of the Army Pamphlet 40-8 ("40-8").

Burström in view of Fennelly et al. disclose the previously described method and system for qualitative respirator fit testing. Burström specifies that the test subjects perform exercises such as moving their heads up and down, side-to-side, and reading the alphabet aloud.

Burström does not specify that the test subjects be prompted to perform such activities during exposure of the test aerosol.

40-8 discloses a method and system for qualitative respirator fit testing wherein a test administrator prompts the test subject to perform a plurality of exercises, while the aerosol is being administered, to ensure a secure mask fit. The administrator receives feedback from the subjects, indicating completion of the test (see page 10).

It would have been obvious to one skilled in the art at the time the invention was made to have provided the system and method for respirator fit testing as disclosed by Burström in view of Fennelly et al., wherein the test subjects are prompted to perform specified activities, as taught by 40-8, to ensure a secure mask fit.

#### *Allowable Subject Matter*

6. Claims 38 and 46 are allowed.

7. Claims 4, 12, 16-20, 22-23, 31 and 39-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### *Response to Arguments*


8. Applicant's arguments with respect to claims 1-46 have been considered but are moot in view of the newly constructed ground(s) of rejection.

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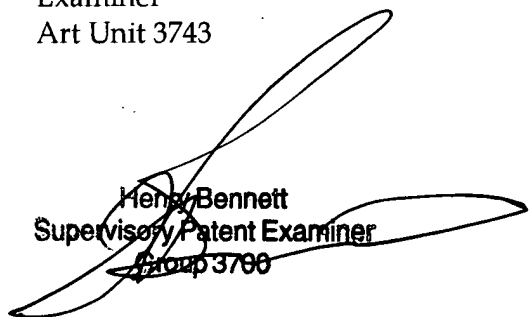
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Amanda F. Wieker  
Examiner  
Art Unit 3743

afw

  
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